

REMARKS/ARGUMENTS

The Office has identified the following groups and is requiring an election of one of the same:

- Group I: Claims 1, 10-12, and 17-19, in part, drawn to a gene;
- Group II: Claims 2, 10-12, and 17-19, in part, drawn to a gene;
- Group III: Claims 3, 10-12, and 17-19, in part, drawn to a gene;
- Group IV: Claims 4, 10-12, and 17-19, in part, drawn to a gene;
- Group V: Claims 5, 10-12, and 17-19, in part, drawn to a gene;
- Group VI: Claims 6, 10-12, and 17-19, in part, drawn to a gene;
- Group VII: Claims 7, 10-12, and 17-19, in part, drawn to a gene;
- Group VIII: Claims 8-12, and 17-19, in part, drawn to a gene;
- Group IX: Claims 13 and 14, drawn to a method; and
- Group X: Claims 15 and 16, drawn to a method.

Moreover, the Office is requiring an election of species depending on which of the above-identified groups is elected.

Applicants elect with traverse Group V, Claims 5, 10-12 & 17-19 (in part), for examination. In addition, Applicants provisionally elect for examination purposes only, with traverse, the following species: AI066764/ lectin, galactoside-binding, soluble, 1 (galectin 1), which is encompassed by at least claim 5.

Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Office if restriction is not required (MPEP §803). The burden is on the Office to provide reasons and/or examples to support any conclusion in regard to patentable distinction (MPEP § 803). Moreover, when citing lack of unity of invention in a national stage application, the Office has the burden of explaining why each group lacks unity with the others (MPEP § 1893.03(d)), i.e. why a single

general inventive concept is nonexistent. The lack of a single inventive concept must be specifically described.

The Office alleges that Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

The technical feature linking Groups 1-10 appears to be a gene selected from the following sequences correlated with the prediction of the postoperative prognosis of primary breast cancer. However, Chu et al. (Journal of Biological Chemistry, Vol. 260, No. 7, pages 4357-4363, 1985, IDS) teach pro-alpha-1 type 3 collagen, see Abstract, p. 4357. Therefore, the technical feature linking the inventions of Groups 1-10 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Annex B of the Administrative Instructions under the PCT, paragraph b (Technical Relationship), states, emphasis added:

The expression "special technical feature" is defined in Rule 13.2 as meaning those technical features that defines a contribution which each of the inventions, ***considered as a whole***, makes over the prior art. The determination is made on the contents of the claims as ***interpreted in light of the description*** and drawings (if any).

Applicants respectfully submit that the Office did not consider the contribution of each invention, ***as a whole***, in alleging the lack of a special technical feature. Applicants also respectfully submit that the Office has not provided any indication that the contents of the claims ***interpreted in light of the description*** were considered in making this allegation. Therefore, the Office has not met the burden necessary to support the assertion of a lack of unity of the invention.

In regard to the election of species requirement, the Office alleges that "[t]he species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record."

Applicants make no statement regarding the patentable distinctness of the species, but note that for restriction to be proper, there must be a patentable difference between the species as claimed. MPEP § 808.01(a). The Office has not provided any reasons or examples to support a conclusion that the species, as claimed, are indeed patentably distinct. Accordingly, Applicants respectfully submit that the restriction is improper, and Applicants' election of species is for examination purposes only.

For the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the requirement for restriction. Applicants therefore request that the requirement for restriction be withdrawn.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits, and early notice thereof is earnestly solicited.

Respectfully Submitted,

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